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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,289	12/19/2000	Luc Montagnier	3495.0068-10	3312

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,289

Applicant(s)

MONTAGNIER ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 31-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01152004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Serial No.: 09/739,289
Applicants: Montagnier, L., et al.

Docket No.: 3495.0068-10
Filing Date: 12/19/00

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 15 January, 2003. Claims 21-29 and 31-38 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement filed 15 January, 2004, has been placed in the application file and the information cited therein has been considered.

35 U.S.C. § 112, Second Paragraph

The previous rejection of claims 31 and 32 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 21-24 and 27-29, 31, and 32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Montagnier et al. (1997) as evidenced by Walsh et al. (1985), Earl et al. (1990), and McGuire

et al. (1992). As previously set forth, Montagnier et al. (1997) disclose monoclonal and polyclonal immunological reagents that recognize HIV-2 gp130-140. This antigen is the monomeric form of the HIV-2 envelope glycoprotein. It has been well-established that both polyclonal and monoclonal immunological reagents that are generated against monomeric viral envelope glycoproteins routinely recognize multimeric forms of the protein (as evidenced by Walsh et al., 1985; Earl et al., 1990; McGuire et al., 1992). Therefore, one of ordinary skill in the art would reasonably expect polyclonal and monoclonal reagents directed against HIV-2 gp130-140 to also bind and recognize dimeric forms of the protein. This result is not surprising considering the numerous immunodominant epitopes shared by both species.

Applicants traverse and submit that the reference relied upon does not disclose antibodies to p200 or p90/80. Applicants are reminded that p200 is the endo-H-treated form of gp300, or dimeric gp140, and p90/80 is the endo-H-treated form of gp140. Thus, these simply represent non-glycosylated forms of the dimer or monomer. Since the envelope glycoproteins are large and complex, it is reasonable to expect that antibodies directed against the native proteins will also bind to endo-H-treated forms of the proteins since many of the epitopes recognized are not contingent upon the glycosylation state of the Env. Accordingly, the rejection is proper and hereby maintained.

Applicants further note that the claims have been amended to state that the antibodies of interest are "specific" for the Env proteins of interest. However, this phrase only requires antibody binding to gp300, p200, or p90/80. It does not exclude antibody binding to monomeric forms of these proteins. One skilled in the art would reasonably expect an Ab "specific" for monomeric forms to also bind to and recognize dimeric or endo-H-treated forms of the Env. Thus, such an antibody would also be "specific" for HIV-2

gp300, p200, and p90/80. Applicants may wish to amend the claim language further, if supported by the disclosure, to distinguish between these two binding events (i.e., wherein said antibodies bind specifically to the dimeric form of the Env, gp300, without binding to the monomeric form of the protein, gp140).

Claims 33, 36, and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kanki et al. (1985) as evidenced by Walsh et al. (1985), Earl et al. (1990), and McGuire et al. (1992). As previously set forth, Kanki et al. (1985) provide polyclonal immunological reagents that recognize the SIV envelope glycoprotein gp160/gp120. These antigens are the monomeric form of the SIV envelope glycoprotein. It has been well-established that both polyclonal and monoclonal immunological reagents that are generated against monomeric viral envelope glycoproteins routinely recognize multimeric forms of the protein (as evidenced by Walsh et al., 1985; Earl et al., 1990; McGuire et al., 1992). Therefore, one of ordinary skill in the art would reasonably expect polyclonal reagents directed against SIV gp160/gp120 to also bind to and recognize dimeric forms of the protein. This result is not surprising considering the numerous immunodominant epitopes shared by both species.

Applicants traverse and submit that the claims have been amended to state that the antibodies of interest are "specific" for SIV p300. As noted in the preceding rejection, this phrase only requires antibody binding to SIV p300. It does not exclude antibody binding to monomeric forms of this protein. One skilled in the art would reasonably expect an Ab "specific" for monomeric forms to also bind to and recognize dimeric or endo-H-treated forms of the Env. Thus, such an antibody would also be "specific" for SIV p300. Applicants may wish to amend the claim language further, if supported by the disclosure, to distinguish between these two

binding events (i.e., wherein said antibodies bind specifically to the dimeric form of the SIV Env, p300, without binding to the monomeric form of the protein, gp140).

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 25 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Montagnier et al. (1997) in view of Galfrè and Milstein (1975). As disclosed *supra*, this teaching provides

monoclonal and polyclonal reagents that are specific to the HIV-2 envelope glycoprotein. This teaching does not disclose labeled antibodies. However, Galfrè and Milstein (1975) provide detailed methodologies for labeling antibodies to facilitate their use in immunodiagnostic assays (e.g., see pp. 26-28). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to label the HIV-2 Env-specific reagents provided by Montagnier et al. (1997) as taught by Galfrè and Milstein (1975). Applicants' arguments have been considered but are not deemed to be persuasive for the reasons of record set forth supra in the rejection of claims 21-24 and 27-29, 31, and 32.

Claims 34, 35, and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kanki et al. (1985) in view of Galfrè and Milstein (1975). As disclosed *supra*, this teaching provides polyclonal reagents that are specific to the SIV envelope glycoprotein. This teaching does not disclose the preparation of monoclonal reagents or labeled antibodies. However, Galfrè and Milstein (1975) provide detailed methodologies for the preparation of monoclonal reagents and labeling protocols to facilitate their use in immunodiagnostic assays (see entire document). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to label the SIV Env-specific reagents provided by Kanki et al. (1985) as taught by Galfrè and Milstein (1975). It would also have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare monoclonal reagents to the SIV Env as taught by Galfrè and Milstein (1975) since this would provide a source of highly specific immunological reagents. Applicants' arguments have been considered but are not deemed to be persuasive for the reasons of record set forth supra in the rejection of

claims 33, 36, and 37.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

02 April, 2004



MARK NAVARRO
PRIMARY EXAMINER